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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/724,870

12/02/2003

Randall S. Hickie

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EXAMINER

NATNITHADHA, NAVIN

ART UNIT

PAPER NUMBER

3735

NOTIFICATION DATE

DELIVERY MODE

12/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/724,870	Applicant(s) HICKLE, RANDALL S.	
	Examiner NAVIN NATNITHITHADHA	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 October 2008 has been entered.

Response to Amendment

2. According to the Amendment, filed 29 October 2008, the status of the claims is as follows:

Claim 1 is currently amended;

Claims 2-7, 9-12, and 14 are as originally filed;

Claims 8, 13, and 15 are previously amended; and

Claims 16-31 are cancelled.

Response to Arguments

3. Applicant's arguments, see Remarks, pp. 5-6, filed 29 October 2008, with respect to the rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Schnitzer et al, U.S. Patent No. 5,692,497 A ("Schnitzer"), in view of Derrick et al, U.S.

Patent No. 5,046,491 A ("Derrick"), and further in view of Allen et al, U.S. Patent No. 6,142,950 A ("Allen"), have been fully considered, but are not persuasive.

As to claim 1, Applicant contends, see Remarks, pp. 5-6, the following:

Schnitzer fails to disclose an electronic controller that automatically gathers additional information when the system alerts the user of a potential problem. The elements of Schnitzer relied upon in the rejection disclose alarm conditions determined based upon certain criteria including relation to predetermined thresholds, but Schnitzer does not teach or suggest an electronic controller that gathers additional information when a display alerts the user, as claimed in claim 1. Derrick fails to supply the deficiency of Schnitzer because Derrick neither teaches or suggests use of a particular visual display to alert the user nor does Derrick teach or suggest any alert system nor an electronic controller that gathers additional information when the display alerts the user. Allen also fails to supply the deficiency of Schnitzer and Derrick because Allen does not teach or suggest a visual display that alerts the user of a potential problem nor an electronic controller that gathers additional information when the display alerts the user. Thus, Applicant respectfully submits that Schnitzer, Derrick, and Allen, alone or in combination, fail to teach or suggest all the elements of claim 1.

However, Schnitzer, which is the primary reference, does, in fact, teach the visual display 132 alerts the user of a potential problem and the electronic controller 22 automatically gathers additional information as follows (see col. 4, ll. 128-34):

The computer or microprocessor control of the invention provides flexibility so far unavailable in existing ventilators, so as to provide, for example, continuous capture of patient data for "real-time" read out or storage for future clinical or research use. The invention also provides for continuous and "real time" monitoring of relevant patient data, e.g., physiological trends, compositions, flows, pressures, volumes, and dynamic compliance data; and responds or notifies the user or connected facility of user-selected warnings, e.g., a warning buzzer, alarm or light, when a selected data characteristic is met.

Thus, even after the user is alerted, the device will continue to capture patient data continuously and in real-time.

Furthermore, Applicant's assertion that "Schnitzer does not teach or suggest an electronic controller that gathers additional information when a display alerts the user, as claimed in claim 1" does not reflect the language of the claims. Claim 1 states "wherein said visual display alerts the user of a potential problem and said electronic controller automatically gathers additional information" (emphasis by Examiner).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer in view of Derrick, and further in view of Allen.

Claims 1-15: Schnitzer teaches a respiratory monitoring system 10 comprising: a patient interface (see schematic in fig. 2) comprising a "patient insert" (i.e. endotracheal tube, ETT, or reverse thrust catheter, RTC, see col. 7, ll. 35-37) 12 and a visual display 132, the nasal cannula 12 comprising at least a first nasal capnography port 19 and a first pressure sensor port 64 (see fig. 1B); a respiratory monitor (flow/pressure bi-direct alert, which detects an incorrect flow and/or an undesirable pressure) 18, comprising a pressure sensor; and an electronic controller (central processor or microprocessor 130) 22; wherein the electronic controller manages a drug delivery device, such as a sedation and analgesia system (see col. 2, ll. 29-35, and col. 4, ll. 34-40); user interface allowing a user to enter inputs corresponding to thresholds relating to inhalation or

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exhalation of the patient (see col. 8, ll. 54-59; wherein pressure waveform analysis and segmentation is used to identify one of respiratory effort and effect (see col. 8, ll. 49-67); wherein alarm conditions are determined based certain criteria including relation to predetermined thresholds (see col. 9, ll. 25-36); LEDs (see col. 3, ll. 52-59); wherein the visual display 132 is updated in real time (see col. 4, ll. 24-34).

In addition, Schnitzer teach the visual display 132 alerts the user of a potential problem and the electronic controller 22 automatically gathers additional information as follows (see col. 4, ll. 128-34):

The computer or microprocessor control of the invention provides flexibility so far unavailable in existing ventilators, so as to provide, for example, continuous capture of patient data for "real-time" read out or storage for future clinical or research use. The invention also provides for continuous and "real time" monitoring of relevant patient data, e.g., physiological trends, compositions, flows, pressures, volumes, and dynamic compliance data; and responds or notifies the user or connected facility of user-selected warnings, e.g., a warning buzzer, alarm or light, when a selected data characteristic is met.

Although Schnitzer does not explicitly teach a nasal cannula, an ear mount and a support band, Schnitzer teaches that the "subsystem 136 is connected for fluid communication with the patient 138, for example, through pneumatic tube (e.g., an ETT) and an RTC (not shown)" (see col. 7, ll. 35-37). However, Derrick teaches an apparatus for gas analysis comprising a nasal cannula 10, an ear mount/support band 28 that is adapted for placement on both ears and provides stability (see figs. 1 and 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schnitzer to have a nasal cannula assembly because the

scope of Schnitzer's invention encompasses other types of fluid communication with patients other than ETT and RTC, such as nasal cannula.

Neither Schnitzer nor Derrick teaches a visual display that "is adapted to be positioned at a suitable location on the body of a patient such that said indicators are visible to a user while simultaneously observing the patient". However, this display feature is well-known in the art. For example, Allen teaches a respiratory monitoring system (apnea screening device) 10 comprising: a nasal interface/cannula (airflow sensor) 11 with an ear mount (adjustable elastic strap worn around the back of the head and around the ears for good stability and comfort) 20; and a display (display means) 16 (see col. 5, ll. 6-24, and col. 6, ll. 26-38). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schnitzer in view of Derrick to have a respiratory monitoring system with a visual display adapted to be positioned at a suitable location on the body of a patient as taught by Allen in order to have a display attached to a patient that is unobtrusive, comfortable, and stable (as stated by Allen, see col. 6, ll. 26-38).

Conclusion

5. This is a continued examination under 37 CFR 1.114. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered prior to the close of prosecution. Accordingly, **THIS ACTION IS MADE FINAL** even though it

constitutes a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
12/19/2008